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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,403	03/30/2006	Graham Cotton	08830-0390US1	2290
23973	7590	08/06/2007		
DRINKER BIDDLE & REATH ATTN: INTELLECTUAL PROPERTY GROUP ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996			EXAMINER RUSSEL, JEFFREY E	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 08/06/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/567,403

Applicant(s)

COTTON, GRAHAM

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-11 and 15-27 is/are rejected.
- 7) ☒ Claim(s) 1 and 12-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20060203</u> | 6) <input type="checkbox"/> Other: _____ |

1. The Sequence Listing filed June 15, 2006 is approved.
2. Claims 2-11 and 15-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase “the terminal activated ester moiety” in claim 2. Note that the independent claim does not require the activated ester moiety to be in a terminal position of the second oligopeptide. There is no antecedent basis in the claims for the phrase “the peptide” in claim 2 or for the phrase “said second polypeptide” in claim 3. Note that the independent claim uses the terminology “first oligopeptide” and “second oligopeptide”. Claim 3, line 3, uses the indefinite article “a” before “second oligopeptide”. Accordingly, it is not clear if the “second oligopeptide” of claim 3 is the same as or different from the “second oligopeptide” recited in claim 1. At claim 4, line 5, “oligopeptide” should be inserted after “precursor” so that step b)i) provides clear antecedent basis for the phrase. There is no antecedent basis in the claim for the phrase “the... second oligopeptides” at claim 4, lines 10-11. Note that the terminology used in step b)ii) is “second oligopeptide molecule”. Claims 4, 8, 15 (to the extent that it depends upon claim 8 or claim 14), 16, 18, 20, and 23 are indefinite because they do not recite Formulas I, II, and III in each claim. Note that whenever feasible, claims are to be complete in and of themselves. See MPEP 2173.05(s). There is no antecedent basis in the claim for the phrases “the oligopeptide molecule” and “said oligopeptide molecule” in claim 20, lines 5-7. Note that lines 1 and 4 of the claim use the terminology “oligopeptide”, and line 3 of the claim uses the terminology “precursor oligopeptide molecule”. Claim terminology needs to be standardized. In claim 25, the relationship among the “first oligopeptide” at line 4 and the “oligopeptide” of the preamble, the

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“oligopeptide molecule” and the “intermediate oligopeptide” of step c), and the “intermediate oligopeptide molecule” and “oligopeptide” of step d), is not clear. There is no antecedent basis in the claims for the phrase “the intermediate oligopeptide molecule” at claim 25, line 9. Note that step c) uses the terminology “oligopeptide molecule” and “intermediate oligopeptide”, but does not use the terminology used in step d). Claim 27 is indefinite because there are no “second” oligopeptides in any of claims 16, 18, 20, 23, and 25. Note that in these claims, an oligopeptide is reacted with a label and not with another oligopeptide.

3. Claims 1-3, 5-7, 9-17, 21, and 24-27 are objected to because of the following informalities: At claim 1, line 4, “a” (second occurrence) should be changed to “an”. At claim 1, line 5, a comma should be inserted after “moiety”. Claim 1 does not end with a period. The period at the end of line 8 should be moved to after the Formulas. At claim 12, line 3, “terminal” should be changed to “terminally”. At claim 14, line 12, “the” should be inserted before “first”. At claim 16, line 3, “a” should be changed to “an”. At claim 25, line 2, “a” should be changed to “an”. Appropriate correction is required.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. *In re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976); *In re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

5. Claims 16, 20-22, and 27 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Nock et al (U.S. Patent Application Publication 2004/0058390). Nock et al teach immobilizing a polypeptide on a support by reacting the polypeptide, which comprises an ester or thioester groups, with the support, which comprises a reactive hydrazine or aminooxy group. The polypeptide comprising a thioester group can be formed from a polypeptide-intein which is treated with a thiol. See, e.g., Figures 1-3 and paragraphs [0020], [0021], [0049], [0050], and [0092]. Because the reactants are the same as those claimed by Applicant, inherently the polypeptide of Nock et al will be linked to the support via a linking moiety having Formula I or II to the same extent claimed by Applicant. Note that Applicant has defined "label molecule" at page 22, lines 11-17, of the specification so as to include solid surfaces.

6. Claim 24 is rejected under 35 U.S.C. 103(a) as being obvious over Nock et al (U.S. Patent Application Publication 2004/0058390). Application of Nock et al is the same as in the above rejection of claims 16, 20-22, and 27. Nock et al do not teach a pH for their

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immobilization reaction. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal pHs for the immobilization reaction of Nock et al because pH is an art-recognized result-effective variable which is routinely determined and optimized in the chemical reaction arts.

7. Claims 15 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Yugari et al (U.S. Patent No. 3,985,617). Yugari et al teach polypeptides which are crosslinked through amino acid sidechains via $-C(=O)-NH-NH-C(=O)-$ groups. See, e.g., column 2, lines 21-53. The crosslinked polypeptides of Yugari et al have the same structure as is required by Formula III. Note that process of making limitations do not impart patentability to product-by-process claims where the product is otherwise taught by the prior art.

8. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by the Bonnet et al article (Tet. Lett., Vol. 41, pages 45-48). The Bonnet et al article teaches reacting lipids comprising active ester groups with hydrazinopeptides in order to link the lipids to the peptides via $-(C=O)-NH-NH-$ groups. See, e.g., Scheme 3.

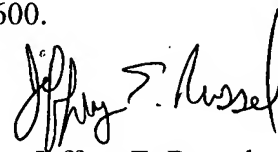
9. Claims 16, 17, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Ryall (U.S. Patent No. 5,965,714). Ryall teaches modifying a polysaccharide with a hydrazide group, and then reacting the modified polysaccharide with a protein in the presence of EDAC and N-hydroxysuccinimide. The EDAC and n-hydroxysuccinimide activate carboxyl groups present on the protein, with which the modified polysaccharide reacts. See, e.g., column 8, lines 46-65, and claim 9. Because the reactants and reaction steps, inherently the method of Ryall will result in a linking moiety having the structure of Applicant's Formula III.

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10. Claim 1 and 12-14 would be allowable if rewritten or amended to overcome the claim objections set forth in this Office action. Claims 2-11, 23, 25, and 26 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, and claim objections set forth in this Office action. Claim 19 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

July 31, 2007